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Model HACCP Program for Fresh and Frozen Soft Shell Blue Crabs Process Flow Chart/Hazard Analysis and Sanitation Standard Operating Procedures (SSOP)

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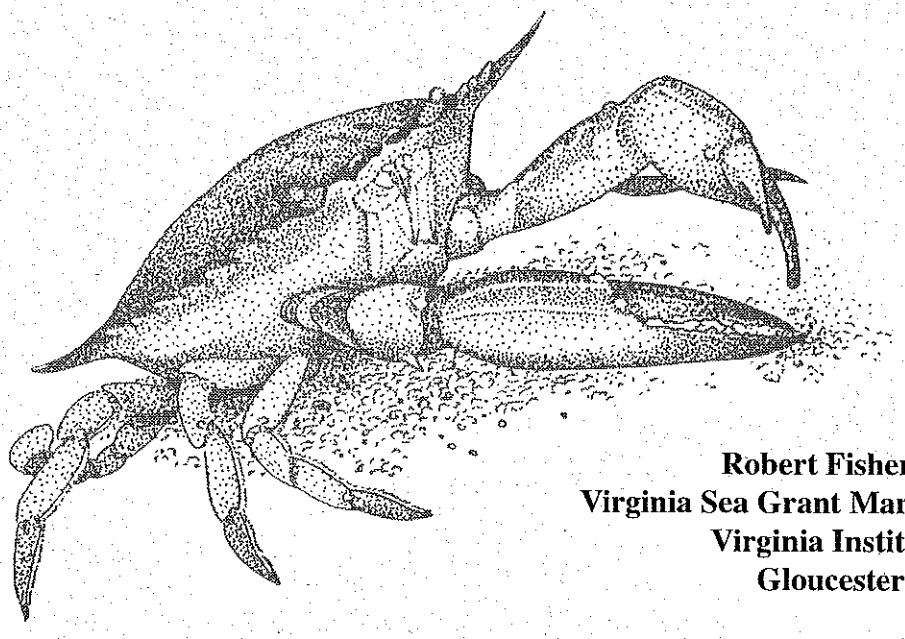
MODEL

HACCP PROGRAM

for

Fresh and Frozen Soft Shell Blue Crabs

Process Flow Chart/Hazard Analysis and Sanitation Standard Operating Procedures (SSOP)



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Introduction

In response to consumer demands and industry requests, the Food and Drug Administration (FDA) has issued seafood regulations based upon preventative measures taken by the processor during food production. These procedures minimize or prevent microbiological, chemical or physical food safety hazards from occurring. This type of seafood inspection program differs from traditional inspection efforts which relied on product testing after it was produced or was already within distribution. This hazard prevention system for ensuring food safety was given the acronym HACCP, which stands for Hazard Analysis and Critical Control Point. The final rule, "Procedures for the Safe and Sanitary Processing and Importation of Fish and Fishery Products," was published in the Federal Register (Vol. 60, No. 242) on December 18, 1995 and became mandatory on December 18, 1997. HACCP is designed to identify potential food safety hazards at specific processing points, to establish controls for those hazards, and to provide monitoring of those controls to prevent those hazards from reaching the consumer. It should be noted that HACCP is not a stand-alone program; it incorporates, and therefore, becomes an extension of Good Manufacturing Practices (GMP).

The FDA HACCP program is an additional mandatory seafood program. It targets food safety hazards, and does not replace on-going federal inspection criteria under the Food, Drug, and Cosmetic Act, a provision which governs food quality and economic fraud issues.

Seafood handlers engaged in the processing and/or importation of seafood products are now required to implement a HACCP program. Exempt from the regulation are harvesting vessels, common carriers for seafood distribution, and retail establishments. The FDA defines processing as the storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading or holding fish or fishery products.

There are seven HACCP principles (or activities) which every processor needs to address:

1) conduct a Hazard Analysis, which entails breaking down the overall process into individual steps or Control Points (CP) and identifying specific potential food safety hazards and measures to control those hazards;

2) identify Critical Control Points (CCP), or steps in the process where application of preventative measures will effectively control the hazard;

3) establish critical limits, or boundaries, at each CCP to ensure that an operation produces a safe product;

4) establish CCP monitoring procedures to assess control of the hazard;

5) establish a course of corrective actions to be taken if monitoring indicates a deviation from established critical limits;

6) establish procedures to verify that the HACCP program is working correctly;

7) establish effective record-keeping that documents the HACCP program.

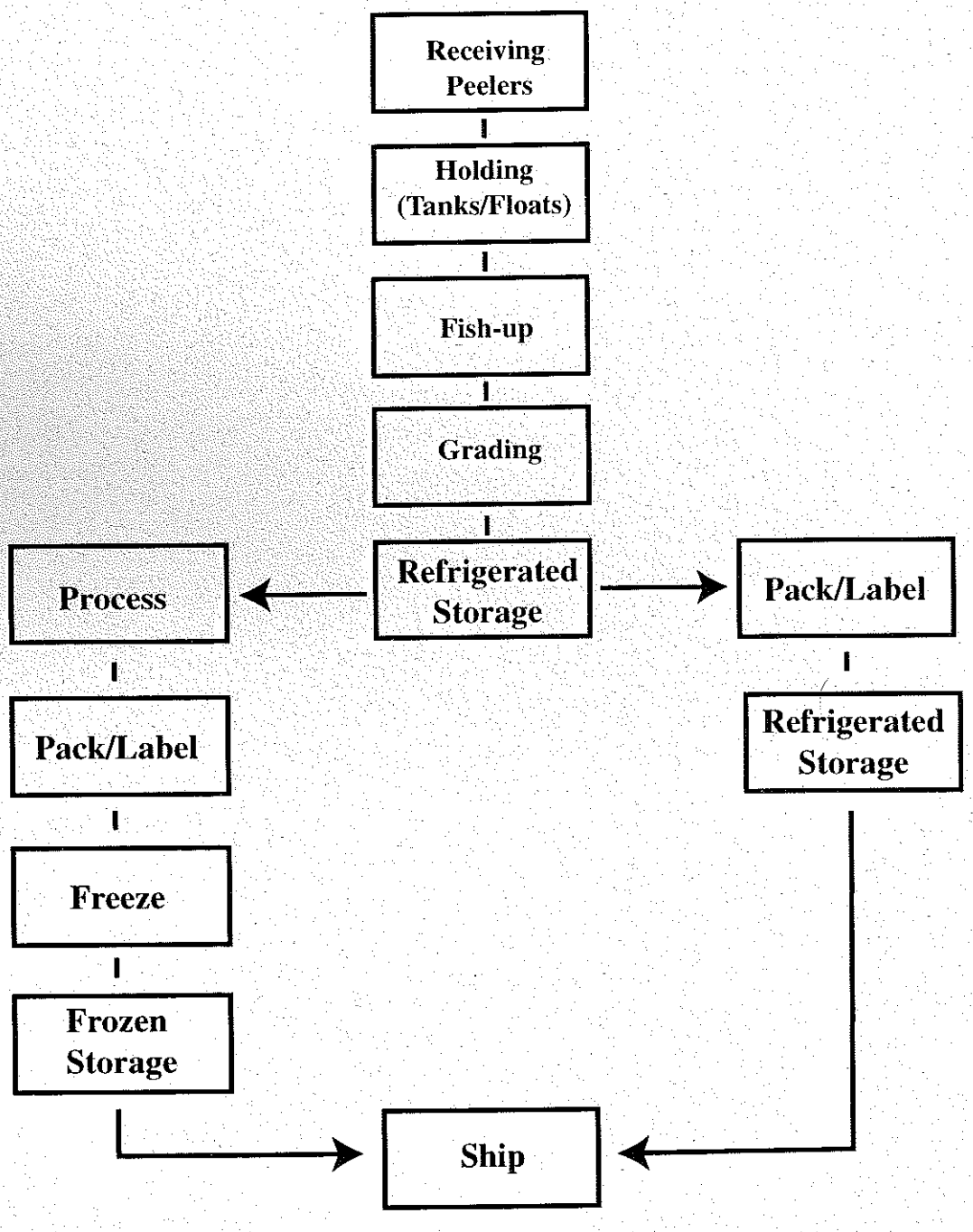
A process flow chart aids in identifying steps within a specific process and facilitates the hazard analysis. If a CCP is identified within a process, then a HACCP "plan" is needed. This would involve principles 2-7. If, after a hazard analysis is performed, no CCPs are identified within a process, a HACCP plan is not needed; however, the processor would still be operating under a HACCP "system" which would focus on Sanitation Standard Operating Procedures (SSOP).

The production of soft crabs has been determined by the FDA to constitute "processing," and therefore is governed by the HACCP regulation. For the production of fresh and frozen soft crabs, no CCPs are identified, and therefore a HACCP plan is not warranted. However, soft crab producers still need to conduct a hazard analysis and implement a SSOP to comply with the regulation. The following generic HACCP system should assist industry in complying with the HACCP regulation. Soft crab producers may use this as a guideline in establishing a HACCP system for a specific location. The following generic program is for the production of fresh and frozen soft crabs only. If a processor decides to enter added-value markets which alter the process, the existing HACCP system needs to be reassessed, and additional potential food safety hazards identified.

SOFTIES, INC.

18 Exuvia Lane
Crabtown, VA

Process Flow Chart
For
Fresh and Frozen Soft Shell Blue Crabs



Hazard Analysis Worksheet
(1 of 2)

(1) Ingredient/ processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What preventative measure(s)can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Receiving	BIOLOGICAL Bacterial pathogens CHEMICAL Environmental contamination PHYSICAL None	Yes No	- Raw crabs can be a source of pathogens. - No documented history of food safety problems in soft crabs from identified chemical hazards. - Obtain peelers from licensed harvesters.	- For frozen crabs, pathogens may not be affected by freezing. However, product to be properly cooked by consumer. - Proper cooking destroys pathogens.	No
Holding	BIOLOGICAL Bacterial pathogens CHEMICAL None PHYSICAL None	No	- Crabs are live. - Cooking by consumer kills pathogens. - Water source either directly from harvesting water or from a potable water source.		
Fish-up	BIOLOGICAL Bacterial pathogens CHEMICAL None PHYSICAL None	No	- Performed on a regular schedule. - All mortalities, empty shells, and debris are removed from the holding water. - Live animal.		

Firm Name: Softies, Inc

Firm Address: 18 Exuvia Lane

Crabtown, VA

Signature: _____

Date: _____

Product Description: Fresh/frozen soft shell crabs (*Callinectes sapidus*)

Method of Storage and Distribution: Refrigerated/frozen

Intended Use and Consumer: Thaw frozen product; fully cook before consumption by general public.

Hazard Analysis Worksheet
(2 of 2)

(1) Ingredient/ processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What preventative measure(s) can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Grading	BIOLOGICAL Pathogen contamination CHEMICAL None PHYSICAL None	No	- Pathogens can be introduced from handling, but controlled by SSOP.		
Processing (soft crab trimming)	BIOLOGICAL Pathogen contamination Pathogen growth CHEMICAL None PHYSICAL None	No No	- Pathogens can be introduced from handling. Controlled by SSOP. - Product to be fully cooked by consumer		
Pack/Label	BIOLOGICAL Bacterial contamination CHEMICAL None PHYSICAL None	No	- Controlled by SSOP. - Product to be cooked.		
Freeze	BIOLOGICAL Bacterial growth CHEMICAL None PHYSICAL None	No	- Not likely to occur due to rapid freezing rate.		
Frozen storage	BIOLOGICAL Bacterial growth CHEMICAL None PHYSICAL None	No	- Product is frozen, pathogen growth unlikely.		
Refrigerated storage	BIOLOGICAL Pathogen contamination Pathogen growth CHEMICAL None PHYSICAL None	No No	- Controlled by SSOP - Product assumed to be cooked.		

Sanitation Standard Operating Procedures (SSOP)

SOFTIES, INC.
C. Sapidus, Owner/Operator
18 Exuviae Lane
Crabtown, VA

These are the Sanitation Standard Operating Procedures for Softies, Inc., a company producing fresh and frozen soft shell blue crabs (*Callinectes sapidus*). Soft shell blue crabs have no documented history of health or human safety problems stemming from identified chemical hazards. Additionally, soft shell blue crabs are a product that is to be fully cooked prior to consumption; there are no known instances of raw consumption. The proper cooking of crabs destroys bacterial pathogens naturally associated with blue crabs. The introduction of bacterial pathogens and/or viruses during processing will be controlled by the following sanitation controls. The owner/operator of Softies, Inc., assumes all responsibility for quality assurance, facility maintenance and production.

1. GOAL: Water that comes into direct contact with soft shell crabs or is used in the shedding system or is used in the manufacturing of ice is derived from a safe and approved source.

PROCEDURE: Softies, Inc., for the production of soft shell blue crabs, will use water in the shedding tanks or floats obtained from a source open for the direct harvest of blue crabs. Other water used in Softies, Inc., that could come in contact with soft shell blue crabs will be potable, obtained either from an approved well or city/county system. Ice manufactured on site will be made from potable water obtained from either an approved well or city/county system. Ice not manufactured on site will be obtained from a source which uses potable water.

2. GOAL: There is no cross-connection between the potable water system and any nonpotable system.

PROCEDURE: Softies, Inc., will perform an inspection prior to each run (at least twice annually) to determine that no cross-connections exist between potable and waste systems. Back-flow prevention valves will be checked for proper functioning at this time. The results of the inspections will be recorded on the sanitation log for each run.

3. GOAL: Source areas for peeler crabs are identified to ensure compliance with any existing harvesting restrictions because of sanitation concerns.

PROCEDURE: Watermen selling peeler crabs to Softies, Inc., will be legally licensed by the Commonwealth of Virginia to harvest peeler crabs and will tell the owner/operator from where the peelers were harvested, prior to the owner/operator accepting peelers. Peelers harvested by Softies, Inc., will not come from any crab harvesting restricted areas. A file of any state or federally implemented harvesting restrictions or regulations will be maintained for reference throughout the production season.

4. GOAL: All soft shell crab contact surfaces and equipment for ice production and storage are designed of such material and workmanship to be easily cleaned and maintained in a sanitary manner. All such surfaces are designed to withstand the environment of its intended use.

PROCEDURE: All shedding facility equipment and utensils will meet any current recommended state and federal standards for their intended use. Softies, Inc., will evaluate the condition of the shedding facility and associated equipment prior to each run. The results of these evaluations will be recorded on the monthly sanitation log for each run.

5. GOAL: All utensils and surfaces of equipment that contact soft shell crabs during "fish-up," grading and/or packaging are cleaned daily and sanitized after each "fish-up" and subsequent processing. ["Fish-up" is the physical removal of soft shell blue crabs from the shedding tanks or floats.]

PROCEDURE: All soft shell crab grading/packaging surfaces and utensils will be cleaned and sanitized. Before each "fish-up," all soft shell crab carrying trays will be cleaned of any debris. Following each "fish-up," soft shell crab carrying trays will be washed with a food-grade or commercial detergent, sanitized and stored properly. Grading and packaging areas will be free of debris prior to any grading/packaging event. Following grading/packaging, the area will be swept clean of debris and washed with food-grade or commercial detergent. Following each "fish-up," grading and/or packaging event, the entire production area will be cleaned of debris.

6. GOAL: The hands of employees are kept clean and sanitary when handling soft shell crabs. All utensils used for grading and/or packaging are kept clean and sanitary.

PROCEDURE: Prior to "fish-up," all employees will wash their hands with an approved soap. A hand dip station will be provided at the grading/packaging area so that employees can sanitize their hands prior to grading or packaging. A dip station for utensils also will be maintained at the grading/packaging area. Sanitizing dips will be either a chlorine-based solution or an Iodophor of sufficient concentration to ensure sanitizing. All utensils will be dipped prior to use and washed and sanitized following grading/packaging events. Hand dips utilizing chlorine will be made up fresh prior to each fish-up to a concentration of approximately 100 ppm. Iodine-based hand dips will be made up at the beginning of each work day and maintained (visually) at a concentration approximately 25 ppm. When applicable, the dip concentrations will be monitored by paper indicator strips and will be recorded. The use and condition of these dips will be recorded on the daily sanitation maintenance log. Employees will be provided periodic training on sanitation procedures and personal hygiene, with records of training retained in the employee training file.

7. GOAL: Any employee of Softies, Inc., who has or may have, by medical examination or owner/operator observation, an illness, infected wound, an open lesion such as a boil or sore, or any other problem that might contaminate live soft shell blue crabs, soft crab contact surfaces or packaging materials, shall be excluded from any operations until the condition is healed or corrected.

PROCEDURE: It is the responsibility of the owner/operator of Softies, Inc., to observe the apparent well-being of all personnel on a daily basis. At any indication of injury or illness that may compromise live soft shell blue crabs due to contamination, the owner/operator will remove that person from the production facility. Observations will be recorded on the daily sanitation maintenance log. Periodic employee training on safe handling of all hazardous materials used will be conducted and entered into the employee training file. Safety data sheets will be kept on file for all hazardous material involved with the production of soft crabs.

8. GOAL: Soft shell crabs, soft shell crab contact surfaces and packaging materials shall be protected from contamination resulting from lubricants, fuel, pesticides, cleaning compounds, sanitizing agents or other chemical or physical contaminants.

PROCEDURE: All cleaning compounds and sanitizing agents, lubricants, fuel, or pesticides will be clearly identified and stored away from the soft shell crab production area or grading and packaging area. The production and grading/packaging areas will be inspected daily for possible contamination sources and to make sure toxic compounds are adequately labeled and stored properly. The results will be documented on the daily sanitation maintenance log.

9. GOAL: Live soft shell blue crabs will be physically separated from incoming peelers during refrigerated storage.

PROCEDURE: Under normal conditions, live soft shell blue crabs are not stored in the same cooler as peeler crabs waiting to be distributed to shedding tanks. Coolers will be inspected daily to ensure soft shell blue crabs are stored properly. This inspection will be recorded on the daily sanitation maintenance log. Additionally, the temperature of the soft shell crab storage equipment will be maintained to provide protection from thermal abuse of the live animals. Temperature inspections will be recorded on the daily sanitation maintenance log. Temperature recording devices will be calibrated at the beginning of each soft crab production season and recorded on a temperature equipment calibration log.

10. GOAL: Adequate, readily accessible toilet facilities that provide for proper sewage disposal shall be available and maintained in a sanitary condition and in good repair.

PROCEDURE: Toilet facilities are provided for employees away from the production, grading and packaging areas. Running water at suitable temperatures will be provided. The condition of the toilet facilities will be inspected daily, and results recorded on the daily sanitation maintenance log.

11. GOAL: No pests are in the grading or packaging area.

PROCEDURE: Control strategies will be implemented to manage the presence of rodents, insects, birds or other pests in the grading or packaging area. Softies, Inc., will be inspected daily for the presence of pests, with observations recorded on the daily sanitation maintenance log.

12. GOAL: The production, grading and packaging areas of Softies, Inc., are designed to minimize the risks of contamination of the live soft shell crabs, contact surfaces and packaging material.

PROCEDURE: The owner/operator of Softies, Inc., will conduct a review of the shedding facility and grading/packaging area layout and physical structure prior to each run to ensure that contamination of any aspect of the production of live soft shell blue crabs does not occur from internal or external sources.Observations will be recorded on the sanitation maintenance log for each run.

13. GOAL: Live soft shell crab production area, grading and packaging areas are free of waste and debris.

PROCEDURE: The empty shells (exuviae) of shed crabs will be removed from all shedding tanks at each "fish-up" and disposed of in a trash can. Any trash or debris generated in the grading and/or packaging process will be cleaned up immediately after these events and disposed of in the proper receptacle. Trash receptacles will be removed from the property of Softies, Inc., in a timely manner to prevent the generation of odors or attraction of pests and disposed of properly. The condition of the trash area will be inspected daily and recorded on the daily sanitation maintenance log.

SOFTIES, INC.
18 Exuvia Lane
Crabtown, VA

Daily Sanitation Maintenance Log for (day/month/year) _____/_____/_____

Employee and Equipment Sanitation	**Fish-up Time_____ Initial____**	**Fish-up Time_____ Initial____**	**Fish-up Time_____ Initial____**	**Fish-up Time_____ Initial____**
Soft crab trays clean				
Hand-dip stations (50-100ppm chlorine; 25ppm I)				
Utensil-dip stations (100ppm chlorine; 25ppm I)				
All equipment clean and sanitized				
Utensils/aprons/gloves clean and sanitized				
All employees have appearance of good health				
Employees have no heavy perfume, cologne, or personal odors				
All employees have clean and sanitary hands				

Sanitation Condition	**Pre-Op** Time _____ Initial ___	**Post-Op** Time _____ Initial ___
All chemicals stored properly		
Shipping and receiving areas clean		
Storage area clean		
Cold storage area cleaned of debris		
Waste cans/trash area clean		
Hot water available at proper locations		
Restrooms clean		
Paper towel, toilet paper, soap adequate in restrooms		
Pest control measures in place		
Shedding tanks clean		

Reviewed by:_____ Date of review

Comment:_____

Month/Year_____

SOFTIES, INC.

18 Exuvia Lane
Crabtown, VA

Sanitation Log for _____Run_____ (year)

Initial	Evaluation
	No cross-connections between potable and wastewater systems
	Production equipment in suitable condition
	Physical condition of shedding facility and layout of equipment suitable to minimize risk of contamination
	Refrigeration and freezer units cleaned

Reviewed by:	Date of review:

Comments:

Month/Year _____

SOFTIES, INC.

18 Exuvia Lane
Crabtown, VA

Weekly Soft Shell Blue Crab Cooler and Freezer Storage Temperature Log

____/____/____ to ____/____/____

DAY	COOLER Pre-Op / Post-Op	FREEZER Pre-Op / Post-Op
Monday	Time ____/____ Temp ____/____ Initial ____/____	Time ____/____ Temp ____/____ Initial ____/____
Tuesday	Time ____/____ Temp ____/____ Initial ____/____	Time ____/____ Temp ____/____ Initial ____/____
Wednesday	Time ____/____ Temp ____/____ Initial ____/____	Time ____/____ Temp ____/____ Initial ____/____
Thursday	Time ____/____ Temp ____/____ Initial ____/____	Time ____/____ Temp ____/____ Initial ____/____
Friday	Time ____/____ Temp ____/____ Initial ____/____	Time ____/____ Temp ____/____ Initial ____/____
Saturday	Time ____/____ Temp ____/____ Initial ____/____	Time ____/____ Temp ____/____ Initial ____/____
Sunday	Time ____/____ Temp ____/____ Initial ____/____	Time ____/____ Temp ____/____ Initial ____/____

Comments:

Month/Year _____

SOFTIES, INC.

18 Exuvia Lane
Crabtown, VA

Temperature Equipment Calibration Log

Instrument type(s): _____
Instrument location(s): _____

Method of calibration:
Cooler_____
Freezer_____

Date Calibrated	Calibration Results (Temp) Cooler Reference / Instrument	Calibration Results (Temp) Freezer Reference / Instrument	Employee Signature	Comments

Reviewed by: _____ Date:_____

SOFTIES, INC.

18 Exuvia Lane
Crabtown, VA

Recall Procedures

All customer complaints are handled by the owner/operator of Softies, Inc. The owner/operator decides if a recall should be initiated, whether it be from a customer complaint or an internal finding. Once the decision for a recall is made, the owner/operator will identify the production dates to be recalled, notify customers affected by the recall, and have all recalled product returned to Softies, Inc.

If the recall is of a serious nature, i.e., illness, death, or injury, the owner/operator will notify the media and the local FDA district office of the recall. If the recall is of such a serious nature, the product will be destroyed.

All product will be labeled with a production date and a lot number. The lot number is recorded on file with the production date, source of product, purchase date, date sold, quantity shipped, and to which customer.